Breast cancer surgery
Principles

Ramanuj Mukherjee
MS DNB  MNAMS  MRCS(England) FMAS
Associate Professor,Surgery.RGKMC
Hony.Asst Secretary WBASl(2010-2012)
Hony Joint Secretary WBASl(2014-2016)
Hony joint secretary (2016-18)
Reviewer Indian Journal of Surgery
Appraiser,NBE.Delhi.
Post Grad Teacher NBE
Surgery in Breast Cancer: The HUNDRED year challenge

1917
Radical Mastectomy

2017
Nipple sparing mastectomy
Breast Conservation therapy
What this talk is about

• The evolution of Surgery
• Mastectomy
• Breast Conservation
• Oncoplastic Breast surgery
• Surgical management of Axilla
The Evolution of Breast Cancer surgery

- 1880: Halsted develops radical mastectomy
- 1900: Radical mastectomy extended in various ways
- 1920: Crile questions ‘more is better’ in Life magazine
- 1940: Fisher and others start trials of less invasive surgery
- 1960: Fisher trial and others reveal no survival advantage
- 1980: 20 year follow-ups confirm findings
- 2000: Rose Kushner publishes book on breast cancer experiences
- 2020: Some clinicians, in professional circles, question need for radical surgery
The Era Of Mastectomy

Halsted Concept
What is Halsted Mastectomy?

- Breast + NAC + tumor
- Skin over breast
- Pectoralis major & minor
- Axillary nodes I,II,III.

✓ Reconstruction by Skin Graft
✓ Poor cosmesis
✓ Promising Survival as first definitive Surgical procedure with sound principles.
Do we need Halsted Mastectomy?

- LABC Pectoral fixity (not T4a)
- T4a tumors(?) needs a staging MRI before surgical decision
- Recurrence breast cancer

- But...Morbidity and outcome needs to be considered.
The followers of Halsted

- Extended mastectomy
- Super radical Mastectomy
- Forequarter disarticulation

- ALL ABANDONED
The Dubious Case for Conservative Operation in Operable Cancer of the Breast

THOMAS J. ANGLEM, M.D., ROBERT E. LEBER, M.D.
When less is More..the era of Modified radical mastectomy

• Standard of Care
• Structures removed
  ✓ Breast + NAC+Tumor
  ✓ Skin overlying Tumor
  ✓ Pectoral fascia
  ✓ Level I,II,III nodes
Patey DH, Dyson WH. The prognosis of carcinoma of the breast in relation to the type of operation performed. British journal of cancer 2(1), 7–13 (1948).
Modified radical mastectomy

• When is this done?
  EBC: as alternative to BCT
  LABC: as standard treatment
  ABC: not done
Modified radical mastectomy

• Incision & Radiation planning
Incison in special situations

Large Breast Women

Small Breast women

Post Oncoplastic Procedure

Post Oncoplastic Procedure
A Bad scar
What is skin sparing mastectomy?
Is Skin sparing mastectomy Safe?

Table 1: Oncological safety of skin-sparing mastectomy for invasive breast cancer – summary of recent studies.

<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Sample size</th>
<th>L.R. (%)</th>
<th>F/U (months)</th>
<th>Notes</th>
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<tbody>
<tr>
<td>Slavin et al⁰</td>
<td>1998</td>
<td>51</td>
<td>2.0</td>
<td>45</td>
<td>26 DCIS cases.</td>
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<tr>
<td>Simmons et al¹³</td>
<td>1999</td>
<td>77</td>
<td>3.9</td>
<td>60</td>
<td></td>
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<tr>
<td>Toth et al⁴</td>
<td>1999</td>
<td>50</td>
<td>0</td>
<td>51.5</td>
<td></td>
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<tr>
<td>Kroll et al⁹</td>
<td>1999</td>
<td>114</td>
<td>7.0</td>
<td>72</td>
<td>T1/T2 tumours.</td>
</tr>
<tr>
<td>Rivadeneira et al¹²</td>
<td>2000</td>
<td>71</td>
<td>5.1</td>
<td>49</td>
<td>Locally advanced.</td>
</tr>
<tr>
<td>Foster et al¹¹</td>
<td>2002</td>
<td>25</td>
<td>4.0</td>
<td>49</td>
<td></td>
</tr>
<tr>
<td>Medina-Franco et al⁶</td>
<td>2002</td>
<td>176</td>
<td>4.5</td>
<td>73</td>
<td>30.6% DCIS.</td>
</tr>
<tr>
<td>Spiegel and Butler⁷</td>
<td>2003</td>
<td>177</td>
<td>5.6</td>
<td>118</td>
<td></td>
</tr>
<tr>
<td>Carlson et al⁵</td>
<td>2003</td>
<td>539</td>
<td>5.5</td>
<td>65</td>
<td></td>
</tr>
<tr>
<td>Gerber et al¹⁴</td>
<td>2003</td>
<td>112</td>
<td>5.4</td>
<td>59</td>
<td>'High risk tumours'</td>
</tr>
<tr>
<td>Downes et al¹⁵</td>
<td>2005</td>
<td>38</td>
<td>2.6</td>
<td>53</td>
<td></td>
</tr>
</tbody>
</table>

International Seminars in Surgical Oncology

Review

Oncological considerations of skin-sparing mastectomy
GH Cunnick¹ and K Mokbel*²
What is Nipple sparing mastectomy?

1. Aware of the possibility of loss of form and function of the NAC.
2. Young, less than 45 years of age.
3. A nonsmoker.
4. Has no prior history of breast surgery or radiation.
5. One for whom adjuvant radiation is not planned apriori.
6. Tumor size is <2.5 cm and is >4 cm from the nipple.
7. Has no documented LVI, axillary lymph nodes or EIC.
Nipple Sparing Mastectomy

ADVANTAGE

1. Scarcity of Terminal duct lobular unit (TDLU) in the nipple permits safe preservation of the tip of the nipple
2. The cosmetic benefit (preservation of body image) following NSM is paramount to a woman’s quality of life following breast surgery
3. Decreased surgical procedures on the ipsilateral and contralateral breast and decreased anesthesia risk provide significant patient advantages
4. Innovative intra-operative radiation techniques (ELIOT) may reduce necrotic complications of the NAC thereby permitting NSM in the therapeutic setting
5. There is no difference in overall survival in the event of a loco-regional breast cancer recurrence
6. Surveillance of the reconstructed breast is possible with Mammography and Breast MRI and does not require take down of the reconstructed breast
Nipple Sparing Mastectomy

Disadvantage

1. The oncologic safety and equivalency of NSM has not been defined in randomized controlled trials (RCTs)
2. No defined or standard incision, operative technique or intra-operative assessment of nipple margin has been established
3. There is a high rate of nipple loss and decreased nipple sensitivity following NSM
4. There is a paucity of data regarding the role, dose and timing of radiation therapy prior to or following NSM
5. The appropriateness of prophylactic NSM in patients with BRCA 1 or 2 mutations is unproven
Specimen of MRM

What to Ask the Surgeon before sending to pathology?

- Quality of Surgery
- Number of nodes
- En block excision
- Label/orientation
- Preop notes with preop chemotherapy details
A good specimen
Specimen of MRM

- Pathology report: what to expect  *Compare Core biopsy report*

**Tumor**
- Size (accurate in mm)
- Margins
- Histology
- Grade (BRS)
- Lymphovascular invasion
- Molecular markers  *ER, PR, her2neu, Ki67 index.*

**Nodes**
- Number dissected
- Number involved
- Extranodal extension

- pTNM
MRM post op care

- 1. Wound care
- 2. Shoulder exercise
- 3. Arm care
- 4. Psychology
- 5. Drains
MRM flap necrosis
MRM drain
Post MRM exercise
Breast Conservation therapy

• When to do
• When NOT to do
• What is your surgical expectation
Breast conservation Surgery

- Wide local excision
- Margin at least 1 cm macroscopic margin
- Incision planning
Society of Surgical Oncology–American Society for Radiation Oncology Consensus Guideline on Margins for Breast-Conserving Surgery With Whole-Breast Irradiation in Stages I and II Invasive Breast Cancer

Meena S. Moran, Susan J. Schmitt, Armand E. Giuliano, Jay R. Harris, Seema A. Khan, Janet Horton, Suzanne Klimberg, Mariana Chavez-MacGregor, Gary Freedman, Nemat Housami, Peggy L. Johnson, and Monica Morrow

See accompanying article on page 1401

ABSTRACT

Purpose
Controversy exists regarding the optimal margin width in breast-conserving surgery for invasive breast cancer.

Methods
A multidisciplinary consensus panel used a meta-analysis of margin width and ipsilateral breast tumor recurrence (IBTR) from a systematic review of 33 studies including 28,162 patients as the primary evidence base for consensus.

Results
Positive margins (ink on invasive carcinoma or ductal carcinoma in situ) are associated with a two-fold increase in the risk of IBTR compared with negative margins. This increased risk is not mitigated by favorable biology, endocrine therapy, or a radiation boost. More widely clear margins do not appreciably decrease the rate of IBTR compared with oncologic tumor. There is no evidence
Breast conservation Surgery

• Surgical expectations
• 1. Pre Operative planning
• 2. Incision planning with surgeon for ABPI/IORT devices
• 3. Cosmetic concerns and outcomes

• Is this the correct patient for BCT?
Breast conservation surgery

Contraindications

• GOAL FOR BCS=<1% RECURRENCE

ABSOLUTE CONTRAINDICATIONS

✓ Locally widespread disease;
✓ Multicentricity;
✓ Diffuse (malignant) micro calcifications;
✓ I or II trimester;
✓ Patients with mutations on BR-CA1 and 2 genes;
✓ Already irradiated thoracic wall.
Breast conservation surgery

Contraindications

Non MOTIVATED PATIENT
Breast Conservation Surgery
4 questions

• 1. Is this Indicated?

• Ans.

“biopsy-proven diagnosis of DCIS or invasive breast cancer clinically assessed as resectable with clear margins and with an acceptable cosmetic result”
Breast Conservation Surgery
4 questions

• 2. what are the Absolute contraindications?
• Ans.

  Current contraindications for BCS include

  a. Early pregnancy
  b. Multicentric tumor involving 2 or more quadrants of the breast
  c. Diffuse malignant/indeterminate microcalcifications
  d. Inflammatory breast cancer
  e. Persistently positive margins of excision

THE AMERICAN SOCIETY OF
Breast Surgeons - Official Statement -
Performance and Practice Guidelines for Breast-Conserving Surgery/Partial Mastectomy
Breast Conservation Surgery
4 questions

• 3. what are relative contraindications?

• Ans.

Relative contraindications for BCS include contraindications to RT (prior breast RT, collagen-vascular disease, morbid obesity, and unavailability), very large breast size (sufficient to pose technical difficulty with breast RT), and very large tumor size relative to breast volume. Of note, neoadjuvant chemotherapy may allow BCS for some patients in whom it would not otherwise be possible, including those with second- or third-trimester pregnancy.
Breast Conservation Surgery
4 questions

• 4. who Does a BCS?
• Ans.
• “Training in the technique of BCS is part of the surgical curriculum in all accredited training programs”
When Does a BCS fail in cosmesis?

- Small breast size
- Ptosis breast
- Large body habitus
- Large tumor size
- Central, Medial, Lower quadrant tumor.
- Segmental distribution
- Resection > 20% breast volume
Clinical trials that you MUST know..
The Origin of NSABP
The National Surgical Adjuvant Breast and Bowel Project (NSABP) is a clinical trials cooperative group supported since its inception by the National Cancer Institute (NCI). We have a more than 50-year history of designing and conducting clinical trials that have changed the way breast cancer is treated, and, more recently, prevented. It was the NSABP’s breast cancer studies that led to the establishment of lumpectomy plus radiation over radical mastectomy as the standard surgical treatment for breast cancer. Were also the first to demonstrate that adjuvant therapy could alter the natural history of breast cancer, increasing survival rates, and the first to demonstrate on a large scale the preventive effects of the drug tamoxifen in breast cancer.

Since its beginning the NSABP has enrolled more than 110,000 women and men in clinical trials in breast and colorectal cancer. We are headquartered in Pittsburgh, Pennsylvania and have research sites at nearly 1000 major medical centers, university hospitals, large oncology practice groups, and health maintenance organizations in the United States, Canada, Puerto Rico, Australia, and Ireland. At those sites and their satellites, more than 5000 physicians, nurses, and other medical professionals conduct NSABP treatment and prevention trials. Their presence at local hospitals and medical facilities means that state-of-the-art clinical trials can be provided to patients near their homes.

The NSABP was one of the first organizations to undertake large-scale studies in the prevention of breast cancer, and our Breast Cancer Prevention Trial (BCPT), which included more than 13,000 women at increased risk for breast cancer, demonstrated the value of the drug tamoxifen in reducing the incidence of the disease in this population. The second prevention trial, the Study of Tamoxifen and Raloxifene (STAR) entered more than 13,000 women to compare the effects of these two drugs in reducing the incidence of breast cancer.

The Office of the Chairman and the NSABP Operations Center are located on the campus of Allegheny General Hospital, and the group’s Biostatistical Center is at the University of Pittsburgh. In addition to federally sponsored studies, the NSABP also conducts research supported by other resources.
NSABP 04

• What was seen?
• For the Evaluation of Radical Mastectomy and Total Mastectomy With and Without Radiation in the Primary Treatment of Cancer of the Female Breast
NSABP B-04

Primary Operable Potentially Curable Breast Cancer n=1665

Clinically Node Negative

- Halsted Radical Mastectomy (includes axillary dissection) 389
- Total Mastectomy + Radiation 386
- Total Mastectomy (ALND if recurrence) 384

Clinically Node Positive

- Halsted Radical Mastectomy (includes axillary dissection) 301
- Total Mastectomy + Radiation 305

No Systemic Adjuvant Therapy (1971-1974)

In the **node-positive** arm, the LRR rates were not significantly different: 16% in patients who underwent radical mastectomy versus 14% in patients who underwent total mastectomy plus radiation (p=0.67).


NSABP B-04
In the **node negative** arm, patients who underwent **total mastectomy plus radiation** had a **lower** rate of local-regional recurrence (LRR; 5%) than did those who underwent radical mastectomy (9%) or total mastectomy alone (13%) (p=0.002).

NSABP 04 at 2002 (25 years FU)
These findings fail to confer a significant survival advantage from removing occult positive nodes at the time of initial surgery or from the addition of loco-regional radiation to total mastectomy.
NSABP B-06

Clinical tumor size <4.0 cm, LN+- (N=2163)

Mastectomy + Axillary dissection (Radical Mastectomy)

Lumpectomy + Axillary dissection

Lumpectomy + Axillary dissection + XRT

N+ : Melphalan and 5-FU (1976-1984)
Mastectomy if lumpectomy margins positive
Negative margins = “no ink on tumor”

OBJECTIVE: To find whether LUMPECTOMY & AXILLARY DISSECTION with or without RADIOTHERAPY is better than TOTAL MASTECTOMY with AXILLARY DISSECTION in early stage breast cancer (stage I & II with tumour size < 4 cm, N0/N1)
The cumulative incidence of a recurrence in the ipsilateral breast 20 years after surgery was 14.3 percent among the women who underwent irradiation after lumpectomy and 39.2 percent among those who underwent lumpectomy without irradiation (P<0.001).

The benefit of radiation therapy was independent of the nodal status.

Patients who received radiation had fewer late recurrences; 73% of recurrences in the lumpectomy plus radiation group were within 5 years while 9% occurred after 10 years compared to the lumpectomy-only group in which 40% of the recurrences were within 5 years and 30% occurred after 10 years.
NSABP B 06

- No significant differences in DFS, DDFS, or OS among groups
After a median follow-up of 20 years, the rate of death from all causes was 41.7 percent in the group that underwent breast-conserving surgery and 41.2 percent in the radical-mastectomy group (P=1.0). The respective rates of death from breast cancer were 26.1 percent and 24.3 percent (P=0.8).
The new “Gods” in Breast cancer

In the last century, we have committed to evidence-based medicine, but in the new millennium, we need to restore humanity.

“In God we trust...all others must have data”
Oncoplastic Breast Surgery

• Goals
  ✓ Complete removal of tumor
  ✓ Negative margin
  ✓ Good to excellent cosmetic outcome
  ✓ Single stage Surgery
Which patient are offered Oncoplastic Sx

<table>
<thead>
<tr>
<th>Patient selection</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Those who wish to undergo partial reconstruction</td>
</tr>
<tr>
<td>2. Those who don’t want replacement techniques</td>
</tr>
<tr>
<td>3. Those who wish to reduct their breasts</td>
</tr>
<tr>
<td>4. Those in whom cancer is confirmed preoperatively</td>
</tr>
<tr>
<td>5. Breast size: moderate to large</td>
</tr>
<tr>
<td>6. Defect size: moderate to large</td>
</tr>
</tbody>
</table>
Oncoplastic breast surgery

- **Volume Displacement**
- **Displacing local tissue**

Volume replacement use of autologous tissue for volume replacement usually as flaps

<table>
<thead>
<tr>
<th></th>
<th>LEVEL I</th>
<th>LEVEL II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume excised</td>
<td>Upto 20%</td>
<td>20-50%</td>
</tr>
<tr>
<td>Skin excision</td>
<td>Not required</td>
<td>Required for breast reshaping</td>
</tr>
<tr>
<td>Mammography</td>
<td>Dense breast</td>
<td>Fatty breast</td>
</tr>
<tr>
<td>Plastic surgery techniques</td>
<td>Not required</td>
<td>required</td>
</tr>
</tbody>
</table>
Glandular Re Shaping
Round Block technique
Glandular Re Shaping
Batwing mastopexy
Reduction mammoplasty
Wise Pattern type
Is your patient Satisfied?

The BREAST-Q conceptual framework

Quality-of-life domains
- Physical Well-being
- Psychosocial Well-being
- Sexual Well-being

Satisfaction domains
- Satisfaction with Breasts
- Satisfaction With Outcome
- Satisfaction With Care
Breast Reconstruction

• Types
• Timing
• Effect of Radiation
Breast reconstruction

• Implant based
• Tissue based
• Pedicle flaps (local: LD flap)
• Pedicle flaps (Distant: TRAM flap)
• Free flap (DIEP flaps)
Timing

A. Immediate reconstruction
Mastectomy and reconstruction
- RT

B. Delayed reconstruction
Mastectomy → Reconstruction
- RT
- 6-12 months

C. Delayed-immediate reconstruction
Mastectomy and TE placement with partial inflation
- NO RT
- Needs RT
- RT
- Expansion
- Final reconstructive surgery
- 2 weeks
- ~3 months
Effect of Radiation on Breast reconstruction

• Needs meticulous planning
• Tangential beam with implants
• Proton therapy is upcoming technology
• Enlistment in clinical trials
Axilla..Surgeon & You.
Definitions

- Axillary clearance
- Axillary Dissection
- Axillary sampling
- Sentinel Node Biopsy
- Reverse Axillary mapping
Indication of ALND

- Node Positive Axillary Disease in Breast cancer
- Positive Sentinel Node biopsy (>2 nodes)
- Axillary recurrence in Post sentinel/Ax. RT
- Occult Breast Cancer with Only Nodal Dis.

- Melanoma Limb/Back/Chest wall
- SCC chest wall/Limb

STAGING

THERAPEUTIC
Contraindications

• EARLY breast cancer with Node negative axilla (sentinel Node Biopsy facility available)
• Palliative mastectomy “Toilet Mastectomy”
• Past H/O axillary radiation or past ALND

• Patient NOT giving Consent for procedure.
Level I

Superiorly: Ax vein
Laterally: Latt dorsi
Medially: Pect minor
Level II

Superiorly: Ax vein
Laterally: Pect Minor
Medially: Pect minor
Defininations

• Axillary clearance
• Axillary Dissection
• Axillary sampling
• Sentinel Node Biopsy
• Reverse Axillary mapping
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Level I

Superiorly: Ax vein
Laterally: Latt dorsi
Medially: Pect minor
Level II

Superiorly: Ax vein
Laterally: Pect Minor
Medially: Pect minor
Complications

**IntraOperative**
- Vascular injury
- Nerve Injury

**Early Post Operative**
- Seroma
- Haematoma
- Frozen Shoulder
- Infections
- Flap necrosis

**Late Post Operative**
- Nerve injury
- Lymphoedema
- Recurrence
# Nerve Injury

<table>
<thead>
<tr>
<th>Nerve</th>
<th>Root value</th>
<th>Function</th>
<th>Manifestation</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Long Thoracic Nerve</td>
<td>C5,6,7</td>
<td>Protraction of scapula</td>
<td>Winging of Scapula</td>
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<tr>
<td></td>
<td></td>
<td>Flexion</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Abduction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thoraco dorsal</td>
<td>C6,7,8</td>
<td>Supply Lat dorsi</td>
<td>Weakness Adduction, Internal rotation</td>
<td>MUST for LD flap</td>
</tr>
<tr>
<td>Intercostobrachial</td>
<td>T2 T3 T4</td>
<td>Sensory in medial aspect of Arm</td>
<td>Hypoesthesia, pain</td>
<td></td>
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The era of Sentinel
Sentinel Lymph node Biopsy

• Concept
• When to do
• Technique
• What to do in Positive sentinel node
Sentinel Node biopsy reported

• One hundred seventy-four mapping procedures were performed using a vital dye injected at the primary breast cancer site.

• Sentinel nodes were identified in 114 of 174 (65.5%) procedures and accurately predicted axillary nodal status in 109 of 114 (95.6%) cases.

• The technique could enhance staging accuracy and, with further refinements and experience, might alter the role of ALND.

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Lymphatic Mapping and Sentinel Lymphadenectomy for Breast Cancer

Armando E. Giuliano, M.D., Daniel M. Kirgan, M.D., J. Michael Guenther, M.D., and Donald L. Morton, M.D.

From the Joyce Eisenberg Keeler Breast Center, John Wayne Cancer Institute at Saint John’s Hospital and Health Center, Santa Monica, California

Objective
The authors report the feasibility and accuracy of intraoperative lymphatic mapping with sentinel lymphadenectomy in patients with breast cancer.

Summary Background Data
Axillary lymph node dissection (ALND) for breast cancer generally is accepted for its staging and prognostic value, but the extent of dissection remains controversial. Blind lymph node sampling or level I dissection may miss some nodal metastases, but ALND may result in lymphedema. In melanoma, intraoperative lymph node mapping with sentinel lymphadenectomy is an effective and minimally invasive alternative to ALND for identifying nodes containing metastases.

Methods
One hundred seventy-four mapping procedures were performed using a vital dye injected at the primary breast cancer site. Axillary lymphatics were identified and followed to the first ("sentinel") node, which was selectively excised before ALND.

Results
Sentinel nodes were identified in 114 of 174 (65.5%) procedures and accurately predicted axillary nodal status in 109 of 114 (95.6%) cases. There was a definite learning curve, and all false-negative sentinel nodes occurred in the first part of the study; sentinel nodes identified in the last 87 procedures were 100% predictive. In 16 of 42 (38.0%) clinically negative/pathologically positive axillae, the sentinel node was the only tumor-involved lymph node identified. The anatomic location of the sentinel node was examined in the 54 most recent procedures; ten cases had only level II nodal metastases that could have been missed by sampling or low (level I) axillary dissection.

Conclusions
This experience indicates that intraoperative lymphatic mapping can accurately identify the sentinel node—i.e., the axillary lymph node most likely to contain breast cancer metastases—in some patients. The technique could enhance staging accuracy and, with further refinements and experience, might alter the role of ALND.
Sentinel Lymph node biopsy
Sentinel Node Biopsy

- Technique
  ✓ Isotope vs. Blue dye
  ✓ Results
The aim of this trial is to report the technical success and accuracy of SLN resection plus ALND versus SLN resection alone.

5611 women with invasive breast cancer were randomly assigned to receive either SLN resection followed by immediate conventional ALND (n=2807; group 1) or SLN resection without ALND if SLNs were negative on intraoperative cytology and histological examination (n=2804; group 2) in the B-32 trial.

SLNs were successfully removed in 97·2% of patients (5379 of 5536) in both groups combined. The overall accuracy of SLN resection in patients in group 1 was 97·1% (2544 of 2619; 95% CI 96·4–97·7), with a false-negative rate of 9·8% (75 of 766; 95% CI 7·8–12·2).
Does SLNB improve QOL?

The ALMANAC trial

A multicenter randomized trial to compare quality-of-life outcomes between patients with clinically node-negative invasive breast cancer who received sentinel lymph node biopsy and patients who received standard axillary treatment.

- Sentinel lymph node biopsy is associated with **reduced arm morbidity** and **better quality of life** than standard axillary treatment and should be the treatment of choice for patients who have early-stage breast cancer with **clinically negative nodes**.

Randomized Multicenter Trial of Sentinel Node Biopsy Versus Standard Axillary Treatment in Operable Breast Cancer: The ALMANAC Trial


*Background:* Sentinel lymph node biopsy in women with operable breast cancer is routinely used in some countries for has been axillary lymph node dissection. This involves considerable resources and causes both acute and chronic complications that include
Multicenter trial comparing overall survival between patients with positive sentinel lymph nodes (SLNs) who did and did not undergo axillary lymph node dissection (ALND).
Z 0011 trial

clinical T1 or T2, N0, M0 breast cancer who underwent BCT and were found to have one or two positive SLNs by H&E evaluation

All patients received WBI (third-field axillary irradiation was not allowed), and recommendations for systemic adjuvant therapy
ACOSOZ 0011 Results

- Premature closure 891 (target 1900)
- After a median follow-up of 6.3 years, only 29 local-regional recurrences were reported in the entire population. The local recurrence rate was 2% in the SLND arm and 4% in the ALND arm. Ipsilateral axillary recurrences were uncommon, occurring in 4 (0.9%) patients in the SLND arm and 2 (0.5%) patients in the ALND arm. The authors found no differences in DFS or OS between the two groups. On the basis of these results, the ACOSOG investigators **concluded that routine use of ALND is not justified and may be safely omitted in selected patients with clinically node-negative disease who have one or two positive SLNs**
**Criticism**

- Significant concern was that the planned sample size was not reached.
- One reason for early closure was that the increased acceptance of screening mammography and improvements in systemic therapy led to an event rate that was lower than anticipated at the time of study design.
- The study was designed to demonstrate the non-inferiority of SLND alone for OS with a p value of 0.008. Because the 95% CIs for the HR did not cross the predefined point at which the treatments would not be considered equal, the results would not be expected to change with a larger sample size.
- The endpoints of total local-regional recurrences, DFS, and OS all numerically favored the SLN group.
ACSOG Guidelines for Management of Sentinel Lymph Node

- **BIOPST RESULTS**
  - Negative sentinel node

- **GUIDELINES**
  - No further axillary treatment, ALND may be omitted

- Positive lymph node at presentation (proven by fnac/core needle biopsy)

- 1 or 2 positive Nodes

- **ALND should be performed**

- 3 or more nodes

- **ALND should be performed**

- **ALND may be omitted if**
  1. primary tumour < 5cm
  2. clinically negative axilla
  3. will receive whole breast radiation and likely systemic therapy
Post ALND lymphedema
Is it necessary to do a ALND after positive sentinel node?
The **AMAROS** trial

• To investigate whether axillary radiotherapy (ART) in patients with primary breast cancer and a tumour-positive sentinel node results in a similar axillary tumour recurrence rate compared with axillary lymph node dissection (ALND), and whether ART results in lower morbidity.
The AMAROS trial

4823 patients registered

17 did not provide informed consent

4806 randomly assigned

2402 assigned to axillary lymph node dissection

2404 assigned to axillary radiotherapy

1658 excluded
  1532 sentinel node negative
  62 sentinel node not identified
  64 other*

744 sentinel-node-positive patients included in intention-to-treat analyses

1723 excluded
  1599 sentinel node negative
  70 sentinel node not identified
  54 other*

681 sentinel-node-positive patients included in intention-to-treat analyses
Lymphoedema was noted significantly more often after ALND than after ART at 1 year, 3 years and 5 years. There were no significant differences in shoulder function or quality of life.

Table 2: Lymphoedema

<table>
<thead>
<tr>
<th>Clinical sign of lymphoedema in the ipsilateral arm</th>
<th>Axillary lymph node dissection</th>
<th>Axillary radiotherapy</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>3/655 (&lt;1%)</td>
<td>0/586 (0%)</td>
<td>0.25</td>
</tr>
<tr>
<td>1 year</td>
<td>114/410 (28%)</td>
<td>62/410 (15%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>3 years</td>
<td>84/373 (23%)</td>
<td>47/341 (14%)</td>
<td>0.003</td>
</tr>
<tr>
<td>5 years</td>
<td>76/328 (23%)</td>
<td>31/286 (11%)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Arm circumference increase ≥10% of the ipsilateral upper or lower arm, or both</th>
<th>Axillary lymph node dissection</th>
<th>Axillary radiotherapy</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>33/655 (5%)</td>
<td>24/586 (4%)</td>
<td>0.497</td>
</tr>
<tr>
<td>1 year</td>
<td>32/410 (8%)</td>
<td>24/410 (6%)</td>
<td>0.332</td>
</tr>
<tr>
<td>3 years</td>
<td>38/373 (10%)</td>
<td>22/341 (6%)</td>
<td>0.080</td>
</tr>
<tr>
<td>5 years</td>
<td>43/328 (13%)</td>
<td>16/286 (6%)</td>
<td>0.0009</td>
</tr>
</tbody>
</table>

Data are n/N (%), unless otherwise specified.
After a median follow-up period of 6.1 years, the 5-year axillary recurrence rate was 0.43% after ALND and 1.19% after ART; the difference was not statistically significant. At 5 years the disease-free survival rate was 86.9% after ALND and 82.7% after ART. Overall survival was 93.3% and 92.5% respectively.